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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,874	05/15/1998	PATRICIA A. BILLING-MEDEL	6106.US.P1	8815

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/079,874

Applicant(s)

BILLING-MEDEL ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A.

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### DETAILED ACTION

**Re:** BILLING-MEDEL *et al*

**Priority Date:** 15 May 1997

1. The amendment filed 7/6/2004 is acknowledged and entered into the record.

Accordingly, claims 1-30 are canceled without prejudice or disclaimer.

2. Claims 31-54 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections Maintained - 35 USC §112, 1<sup>st</sup> paragraph***

4. The rejection of claims 31-54 under 35 USC § 112, 1<sup>st</sup> as lacking written description is maintained for the reasons of record. Applicant argues that the written description is sufficient for the claimed invention because the specification defines a method of hybridizing the polynucleotide to any sequence that is at least 50% identical to sequences of SEQ ID Numbers. Applicant further states that the method itself is drawn to "a method of detecting target polynucleotides and not the target polynucleotides themselves." Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The claims are drawn to a method of detecting the presence of a target polynucleotide in a test sample comprising contacting the test sample with at least one isolated polynucleotide of SEQ ID Nos.: 1-12 followed by detecting the presence of said target polynucleotide. While the specification provides adequate written description for the sequence represented by SEQ ID No: 12 which represents the UT116 gene, there is

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no disclosure of any activity (nor any method of analyzing any activity) or structural information of any of those "target" sequences which the method intends to detect as claimed. Furthermore, there is no core structure or identifiable characteristic for recognizing the target polynucleotides as claimed. Aside from the 50% identity to the sequences represented by SEQ ID Nos.: 1-12, the skilled artisan cannot determine any characteristics associated with the "target" polynucleotide, because the genus of compounds claimed are extensive and would be highly variant. Furthermore, the claims do not specify any hybridization condition that would help limit the type and numbers of polynucleotides to which the sequences of SEQ ID Nos.: 1-12 would bind. Thus the genus of compounds encompassed by the claims are extensive and the specification has not meet sufficient written description to claim the broad genus.

Applicant also argues that the method of detection or type of detection step is not required because any detection step is encompassed so long as one of skill in the art would be capable of accomplishing said detection. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Because the claims nor the specification have clearly delineated the type of detection, or the hybridization conditions, and has only defined the nucleotides targeted as those that are at least 50% identical to those of SEQ ID No: 1-12, one of skill in the art would reasonable expect a high degree of variation between the nucleic acid sequences detected. As such, the skilled artisan cannot possible envision what nucleotide sequences would fall within the scope of the detection method and the specification has not defined any specific sequences or structures that are representative of the highly

variant nucleotide "target" sequences claimed. The mere fact that the sequences targeted would have at least 50% identity in it of itself is insufficient to describe the genus of nucleotides claimed from the method.

With regard to applicant's arguments in point C, it is understood that claims are drawn to a method of detecting target sequences and not specifically drawn to the target polynucleotides *per se*, the method still involves the detection of "target" sequences that have not been characterized or defined by any recognizable structure. One of skill in the art would still require knowledge of the types of nucleotide sequences detected by the method, because the broad genus of nucleotides claimed are highly variant due to the lack of hybridization criteria needed to obtain a defined set of sequences. The mere fact that the specification teaches some common techniques for the detection of target sequences alone does not give the skilled artisan sufficient description of what types of sequences are detected in the claimed method. At this point, the method claimed potentially detects any sequence so long as it has at least 50% homology to the claimed SEQ ID Nos.: 1-12. This highly variant and diverse set of sequences have not been adequately disclosed in the specification.

Thus given the limited disclosure with regard to the "target" sequence detected in the claimed method and the limited disclosure with regard to hybridization language that would decrease the variability of the sequences detected, the written description rejection of record is maintained.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 31-32,34-36,38-41,43-48, and 50-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young J (US Patent 5,856,136, filed 1996). Au-Young teaches a method of detecting a sequence that is identical to that of SEQ ID No: 4 (see attached exhibit A) of the instant invention, wherein the detection step is accomplished by contacting a target polynucleotide with an isolated polynucleotide which is identical to SEQ ID No: 4. It is also contemplated by Au-Young to perform such detection methods with mRNA, PCR, and using primers (see col. 16, lines 63-67 and cols. 17-18). Au-Young also teaches that the method can be performed on a solid phase (see Col. 17, line 4) and can be detected using measurable signals (see col. 17, line 10, for example). Thus the claims of the instantly claimed invention are anticipated.

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**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 7/6/2004.**

***Conclusion***


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
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September 27, 2004

  
**GARY NICKOL**  
**PRIMARY EXAMINER**